NORTHERN BORDER CUSTOMS BROKERS ASSOCIATION, INC.

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May 13, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Via Overnight mail

RE: Comments on Interim Final Rule on Prior Notice of Imported Food, Docket No. 2002N-0278

Dear Sirs/Madams:

The Northern Border Customs Brokers Association (NBCBA) continues to endorse and support the actions of the U.S. Food and Drug Administration to ensure that food entering the commerce of the United States is safe from terrorist acts. We do wish to offer constructive comments on the interim final rules and our experiences with these rules since their implementation on December 12, 2003.

We therefore respectfully submit the following comments, first addressing the specific questions posed by FDA on C-TPAT/FAST and followed by our experiential observations.

Response to C-TPAT/FAST Questions

Food product subject to FDA's prior notice requirements should be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST. Currently, the benefits with full expedited processing are: Use of the FAST lane and a 30-minute Prior Notice (PN) timeframe. Additionally, information transmission benefits will become available with the Customs and Border Protection (CBP) e-truck manifest and its reduced data elements and examinations. Further, all C-TPAT certified shippers and their products should be eligible for reduced data element reporting at the time of Prior Notice (PN) by virtue of having successfully passed the C-TPAT validation process. The product

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information (Harmonized Tariff Schedule number, Product Code, manufacturer's registration numbers, etc) should be part of the pre-filed information profiles under FAST.

Without these types of benefits, participation will be discouraged when contrasted to the resource commitment and expense associated with participation.

Under CBP Advance Electronic Cargo Information rule, the time element for FAST participants is established at 30 minutes. To have two different time standards for the same mode of transportation only serves to create confusion. In the case of less than truckload (LTL) and small package carriers, the possibility could exist that freight contained in the same trailer would require two different reporting time frames, one for CBP and the other for FDA if the reporting timeframes were not aligned.

In order to minimize confusion, the phase-in periods of shorter timeframes should be aligned and harmonized between FDA and CBP.

The basic processes for C-TPAT security and verification should be the same regardless of the federal agencies involved. Agencies may have their own additional requirements for specific products for which they have oversight and elevated concerns, but as a general rule, all other government agencies with oversight should align their processes, timeframes and benefits offered to program participants. Participation in these programs should continue to be voluntary.

Regarding verification of compliance with FDA registration requirements, the verification should have be part of FDA's C-TPAT validation. Included in this process should be on-site visits, inspections, and audits as deemed necessary.

With regard to FDA's question about exclusion of certain foods by product category, participation and inclusion should be determined by a company's ability to meet the program standards set by the particular government agency.

FDA should offer prior notice submission outreach training, as such programs are insightful and always welcome.

NBCBA Comments on Interim Final Regulations Experiences

Prior Notice Confirmation Number (PNC): Under today's PN process, a prior notice is required for each separate and distinct food product and a PNC is returned for each prior notice. For example, if a shipment consists of multiple food products, then the reporting party receives multiple PNC's that cover one shipment. This return of multiple PNC's does not align well with the commercial realities of international trade where the focus is on the entire shipment, not its individual components. Further, reporting of multiple PNC's requires creation of new data fields or expansion of existing fields in trade software and on transportation documents. We recommend that FDA return a single PNC that encompasses the entire shipment.

FDA's definition of submitter: The interim rule defines the submitter as: "Any person with knowledge of the required information may submit prior notice for an article of food.

This person is the submitter. The submitter may also use another person to transmit the required information on his or her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person (21 CFR 1.278)." The information required for the "submitter" is not only the corporate name and address but an individual's name, telephone number, fax number and e-mail address. We contend this level of detailed information is redundant. The information should already exist in the FDA registration database. Further, in today's employment market, individuals frequently seek other employment opportunities, thereby making this level of specificity in any database subject to review and update at any given time. This results in the potential for inaccurate information to be transmitted, as well as creating an on-going maintenance requirement. The name of the corporation should be sufficient. We ask that FDA change their requirement and allow for a corporation to be reported as a submitter.

When a Prior Notice is transmitted via either the Cargo or Border Cargo Selectivity application, the date should be moved from ACS to OASIS regardless of the ETA date: NBCBA has learned that if a shipment's estimated time of arrival date is greater than that day's date, the data is not transmitted to FDA's OASIS immediately. The data is held and transmitted via an ABI batch process only at pre-determined times later that evening. However, if a Prior Notice is submitted with an ETA of the same date, the data is transmitted immediately.

In today's international trade environment, this difference in timing has become unacceptable, as many shippers are providing advance documentation so they can stage their next day's shipments to avoid border delays and additional expense. The staging, which is intended to ensure compliance with FDA's Prior Notice Regulations, is dependant upon receipt of the Prior Notice confirmation number.

Port diversions and inconsistence between agencies: Often, diversions from one port of entry to another port of entry occur for legitimate reasons. Although, the FDA PN system is designed to allow a shipment to be diverted to a port other than the intended port of entry reported in the PN, the CBP ABI system precludes the CBP entry from being accepted at other than the reported port of entry. When this occurs, the CBP entry and original PN must be deleted and a new entry must be submitted with a new PN creating a new timeframe. This limitation makes it difficult to comply with the BTA timeframes for a PN submitted through ABI. We recommend that FDA ask CBP to change their ABI system to provide for port diversion functionality.

Line Value and Quantity Reporting for Prior Notice: This level of detail reporting is time consuming and burdensome. We fail to see how this level of detail, e.g.; reporting by package size, will aid FDA's ability to protect the US food supply chain. If a product is tainted, FDA will be interested in all of the product regardless of package size.

Section 321 Shipments: FDA and CBP should clarify in detail how shipments that qualify for CBP release under this provision and also require prior notice will be handled under full enforcement.

Removal of BRASS C4 codes: As a means of ensuring that it would receive prior notice of each shipment of imported food, FDA worked with CBP in removing BRASS privileges for

parties who import "articles of food" subject to the prior notice requirements. We believe FDA and CBP's actions in this area have been too broad in instances involving imported product capable of more than one use; i.e., capable of use as food, and capable of use as non-food. In a number of cases, parties import large numbers of shipments of a given product and rely on BRASS privileges to move that product efficiently through the border from Canada into the United States. Over 99% of the time, the product is used for non-food purposes; it is only rarely used for food purposes. Because of this extremely infrequent use of the product for food purposes, CBP and FDA's policy of removing BRASS privileges for food products results in loss of C4 codes for the product. Hundreds of shipments of non-FDA/BTA-regulated goods released via the expedited BRASS program must now be manually prepared for cargo release, simply because less than 1% of the imported shipments of such merchandise are used for food purposes. Common sense needs to be applied here. BRASS privileges should not be removed for products of this nature. FDA should amend its regulations to state that, where a product has both food and non-food uses, the importer is required to file prior notice when the imported product is intended for use as a food. As a policy matter, FDA and CBP should require BRASS participants to file PN, and make a regular BCS release, for such merchandise; where product is imported for non-food purposes, importers should be able to continue to use BRASS. They should not have such privileges removed because a tiny minority of their shipments happen to be put to food-related use.

Contingency Planning: The Trade's experience with the system outage on March 15, 2004 was less than satisfactory. The outage started with ABI, which included the connection to OASIS. As everyone shifted to using the Prior Notice System Interface (PNSI), PNSI was overwhelmed and failed.

Further, on the evening of May 12, 2004, in anticipation of the Phase III enforcement period, the Trade Community once again overwhelmed PNSI with a large number of PN submissions. Our projected concern is that when the final enforcement implementation occurs in August 2004, that PNSI will not be able to handle the volume.

FDA and CBP need to formulate and communicate a realistic contingency plan for commercial importations that takes into account CBP ABI downtime, FDA OASIS downtime and broker downtime. None of the solutions should include a dependency on PNSI as experience has shown that PNSI was intended for the casual importer and never intended for commercial operations.

Enforcement: There are continued technical problems with the systems for providing Prior Notice. PNSI is not a commercially reliable system, the CBP WP module has as yet to deliver the anticipated solutions. Until recently, ABI errors or warnings have not been returned to the transmitter resulting in a less than effective compliance outreach program. There has been a significant lack of compliance outreach to both transmitters and/or submitters. These shortcomings have resulted in the importing community's high level of concern about full implementation and enforcement of the BTA. FDA and CBP should delay their final phase of enforcement to compensate for the failure to provide effective and timely compliance information as committed to in the published Phased In Enforcement Plan. NBCBA recommends that FDA and CBP extend their final phase of enforcement for a

comparable time equal to the originally proposed timeframes to allow sufficient outreach to all trading partners.

NBCBA would like to continue to work with FDA and CBP to refine the PN process so that there will be minimal adverse impact on international trade while continuing to satisfy the mandate that FDA has been given to protect the safety and security of the US food supply.

Yours truly,

Leman G. Bown, Jr.